

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (original): An implantable device comprising a reticulated resiliently-compressible elastomeric matrix.

Claim 2 (original): The implantable device of claim 1, wherein the implantable device is biodurable for at least 29 days.

Claim 3 (previously presented): The implantable device of claim 1, wherein the elastomeric matrix comprises a polycarbonate polyurethane, a polycarbonate polyurethane-urea, or any mixture thereof.

Claim 4 (original): The implantable device of claim 3, wherein the implantable device is biodurable for at least 6 months.

Claim 5 (previously presented): The implantable device of claim 1, comprising a reticulated elastomeric matrix comprising a plurality of pores, the pores having an average diameter or other largest transverse dimension of at least about 100 μm .

Claim 6 (original): The implantable device of claim 3, wherein the pores have an average diameter or other largest transverse dimension of from greater than 250 μm to about 900 μm .

Claim 7 (original): The implantable device of claim 1, comprising a reticulated elastomeric matrix comprising a plurality of pores, the pores having an average diameter or other largest transverse dimension of from about 275 μm to about 900 μm .

Claim 8 (previously presented): The implantable device of claim 1, comprising a reticulated elastomeric matrix comprising a plurality of pores, the pores having an

average diameter or other largest transverse dimension of from greater than 300 μm to about 700 μm .

Claim 9 (previously presented): The implantable device of claim 1, comprising a resiliently-compressible elastomeric matrix such that the implantable device, when compressed from a relaxed configuration to a first, compact configuration for delivery via a delivery-device, expands to a second, working configuration, *in vitro*, at least about 50%, optionally at least about 80%, of the size of the relaxed configuration in at least one dimension.

Claim 10 (previously presented): The implantable device of claim 9, wherein the recovery properties of the elastomeric matrix are such that a dimension of the second, working configuration is within about 50% of a relaxed dimension of the relaxed configuration after compression to from about 90% to about 10% of the relaxed dimension and wherein the elastomeric matrix has a compressive strength at 50% compression of from about 1 psi (about 700 kg/m^2) to about 200 psi (about 140,000 kg/m^2), a tensile strength of from about 1 psi (about 700 kg/m^2) to about 75 psi (about 52,500 kg/m^2) and an ultimate tensile elongation of at least about 76%.

Claim 11 (previously presented): The implantable device of claim 1, wherein the elastomeric matrix has a compression set after 22 hours compression at about 25°C to 50% of its thickness in one dimension of not more than about 30%, optionally not more than about 10%.

Claim 12 (previously presented): The implantable device of claim 1, wherein the elastomeric matrix comprises polycarbonate, polysiloxane, polyurethane, hydrocarbon, copolymers thereof, or any mixture thereof.

Claim 13 (previously presented): The implantable device of claim 1, wherein the reticulated elastomeric matrix is configured to permit cellular ingrowth and proliferation into the reticulated elastomeric matrix.

Claim 14 (withdrawn): A process for producing an elastomeric matrix comprising a polymeric material having a reticulated structure, the process comprising:

- a) fabricating a mold having surfaces defining a microstructural configuration for the elastomeric matrix;
- b) charging the mold with a flowable polymeric material;
- c) solidifying the polymeric material; and
- d) removing the mold to yield the elastomeric matrix.

Claim 15 (withdrawn): The process of claim 14, wherein the mold is a sacrificial mold and is removed by melting, dissolving or subliming the sacrificial mold.

Claim 16 (withdrawn): The process of claim 14, wherein the sacrificial mold comprises a plurality of particles interconnected one with another at multiple points on each particle, wherein the flowable polymeric material is contained within the interstices between the particles.

Claim 17 (withdrawn): The process of claim 16, wherein the particles comprise a first material having a melting point at least 5°C lower than the softening temperature of the polymeric material that is contained within the interstices where, optionally, the first material comprises a hydrocarbon wax.

Claim 18 (withdrawn): The process of claim 16, wherein the particles comprise an inorganic salt, a sugar, a starch, or any mixture thereof.

Claim 19 (withdrawn): The process of claim 18, wherein the particles comprise starch and the starch is removed enzymatically.

Claim 20 (withdrawn): The process of claim 18, wherein the polymeric material comprises a solvent-soluble thermoplastic elastomer, the flowable polymeric material comprises a solution of the thermoplastic elastomer in a solvent, and the solvent is evaporated to solidify the thermoplastic elastomer.

Claim 21 (withdrawn): The process of claim 20, wherein the thermoplastic elastomer is selected from the group consisting of polycarbonate polyurethanes, polycarbonate polyurethane-ureas, polysiloxane polyurethanes, polysiloxane polyurethane-ureas, hydrocarbon polyurethanes, hydrocarbon polyurethane-ureas, polycarbonate-polysiloxane polyurethanes, polycarbonate-polysiloxane polyurethane-ureas, polycarbonate-hydrocarbon polyurethanes, polycarbonate-hydrocarbon polyurethane-ureas, polycarbonate-polysiloxane-hydrocarbon polyurethanes, polycarbonate-polysiloxane-hydrocarbon polyurethane-ureas, polysiloxane-hydrocarbon polyurethanes, polysiloxane-hydrocarbon polyurethane-ureas, and or any mixture thereof.

Claim 22 (withdrawn): A process for producing an elastomeric matrix having a reticulated structure, the process comprising:

- a) coating a reticulated foam template with a flowable resistant material, optionally a thermoplastic polymer or a wax;
- b) exposing a coated surface of the foam template;
- c) removing the foam template to yield a casting of the reticulated foam template;
- d) coating the casting with an elastomer in a flowable state to form an elastomeric matrix;

e) exposing a surface of the casting; and
f) removing the casting to yield a reticulated elastomeric matrix comprising the elastomer.

Claim 23 (withdrawn): The process of claim 22, wherein the elastomer is a thermoplastic elastomer selected from the group consisting of polycarbonate polyurethanes, polycarbonate polyurethane-ureas, polysiloxane polyurethanes, polysiloxane polyurethane-ureas, hydrocarbon polyurethanes, hydrocarbon polyurethane-ureas, polycarbonate-polysiloxane polyurethanes, polycarbonate-polysiloxane polyurethane-ureas, polycarbonate-hydrocarbon polyurethanes, polycarbonate-hydrocarbon polyurethane-ureas, polycarbonate-polysiloxane-hydrocarbon polyurethanes, polycarbonate-polysiloxane-hydrocarbon polyurethane-ureas, polysiloxane-hydrocarbon polyurethanes, polysiloxane-hydrocarbon polyurethane-ureas, or any mixture thereof.

Claim 24 (withdrawn): A lyophilization process for producing an elastomeric matrix having a reticulated structure, the process comprising:

a) forming a solution comprising a solvent-soluble biodegradable elastomer in a solvent;
b) at least partially solidifying the solution to form a solid, optionally by cooling the solution; and
c) removing the non-polymeric material, optionally by subliming the solvent from the solid under reduced pressure, to provide an at least partially reticulated elastomeric matrix comprising the elastomer.

Claim 25 (withdrawn): The process of claim 24, wherein the elastomer is a thermoplastic elastomer selected from the group consisting of polycarbonate polyurethanes,

polycarbonate polyurethane-ureas, polysiloxane polyurethanes, polysiloxane polyurethane-ureas, hydrocarbon polyurethanes, hydrocarbon polyurethane-ureas, polycarbonate-polysiloxane polyurethanes, polycarbonate-polysiloxane polyurethane-ureas, polycarbonate-hydrocarbon polyurethanes, polycarbonate-hydrocarbon polyurethane-ureas, polycarbonate-polysiloxane-hydrocarbon polyurethanes, polycarbonate-polysiloxane-hydrocarbon polyurethane-ureas, polysiloxane-hydrocarbon polyurethanes, polysiloxane-hydrocarbon polyurethane-ureas, or any mixture thereof.

Claim 26 (withdrawn): A polymerization process for preparing an elastomeric matrix, the process comprising admixing:

- a) a polyol component,
- b) an isocyanate component,
- c) a blowing agent,
- d) optionally, a crosslinking agent,
- e) optionally, a chain extender,
- f) optionally, at least one catalyst,
- g) optionally, a surfactant,
- h) optionally, a viscosity modifier, and
- i) optionally, a cell opener;

to provide the elastomeric matrix.

Claim 27 (withdrawn): The process of claim 26, wherein the polyol component is liquefied prior to admixing.

Claim 28 (withdrawn): The process of claim 26, wherein a first admixture comprising the polyol and isocyanate components is formed by admixing the polyol component

and the isocyanate component; a second admixture comprising the blowing agent and, optionally, the catalyst is formed by admixing the blowing agent and the optional catalyst; and the first admixture and the second admixture are admixed.

Claim 29 (withdrawn): The process of claim 26, wherein the polyol component comprises a polycarbonate polyol, hydrocarbon polyol, polysiloxane polyol, poly(carbonate-co-hydrocarbon) polyol, poly(carbonate-co-siloxane) polyol, poly(hydrocarbon-co-siloxane) polyol, or any mixture thereof.

Claim 30 (withdrawn): The process of claim 29, wherein the polyol component comprises difunctional polycarbonate diol.

Claim 31 (withdrawn): The process of claim 30, wherein the difunctional polycarbonate diol is 1,6-hexamethylene polycarbonate diol.

Claim 32 (withdrawn): The process of claim 26, wherein the isocyanate component comprises tetramethylene diisocyanate, cyclohexane-1,2-diisocyanate, cyclohexane-1,4-diisocyanate, hexamethylene diisocyanate, isophorone diisocyanate, methylene-bis-(p-cyclohexyl isocyanate), p-phenylene diisocyanate, 4,4'-diphenylmethane diisocyanate, 2,4'-diphenylmethane diisocyanate, m-tetramethylxylene diisocyanate, or any mixture thereof.

Claim 33 (withdrawn): The process of claim 32, wherein the isocyanate component comprises diphenylmethane diisocyanate, wherein the diphenylmethane diisocyanate is a mixture of at least about 5% by weight of 2,4'-diphenylmethane diisocyanate with the balance mainly 4,4'-diphenylmethane diisocyanate.

Claim 34 (withdrawn): The process of claim 32, wherein the average number of isocyanate groups per molecule in the isocyanate component is about 2.

Claim 35 (withdrawn): The process of claim 32, wherein the average number of isocyanate groups per molecule in the isocyanate component is greater than 2.

Claim 36 (withdrawn): The process of claim 35, wherein the average number of isocyanate groups per molecule in the isocyanate component is greater than about 2.2.

Claim 37 (withdrawn): The process of claim 32, wherein the isocyanate component has an isocyanate index and wherein the isocyanate index is from about 0.9 to about 1.1.

Claim 38 (withdrawn): The process of claim 37, wherein the isocyanate index is from about 0.98 to about 1.02.

Claim 39 (withdrawn): The process of claim 37, wherein the isocyanate index is from about 0.9 to 1.029.

Claim 40 (withdrawn): The process of claim 26, wherein the blowing agent is water.

Claim 41 (withdrawn): The process of claim 26, wherein the catalyst is present and is a tertiary amine.

Claim 42 (withdrawn): The process of claim 26, wherein the surfactant is present and is a silicone-based surfactant.

Claim 43 (withdrawn): The process of claim 26, wherein the viscosity modifier is present and is propylene carbonate.

Claim 44 (withdrawn): The process of claim 61, wherein the reticulation is by combustion reticulation.

Claim 45 (withdrawn): The process of claim 44, wherein the combustible atmosphere comprises a mixture of hydrogen and oxygen.

Claim 46 (withdrawn): A process for preparing a reticulated composite elastomeric implantable device, the process comprising endoporusly coating a reticulated elastomeric matrix with a coating material selected to encourage cellular ingrowth and proliferation.

Claim 47 (withdrawn): The process of claim 46, wherein the coating material comprises a foamed coating of a biodegradable material, the biodegradable material comprising collagen, fibronectin, elastin, hyaluronic acid, a bioabsorbable aliphatic polyester, or any mixture thereof.

Claim 48 (withdrawn): A method of treating a vascular malformation, the method comprising:

- a) compressing the implantable device of claim 1 from a relaxed configuration to a first, compact configuration;
- b) delivering the compressed implantable device to the *in vivo* site of the vascular malformation via a delivery-device; and
- c) allowing the implantable device to expand to a second, working configuration at the *in vivo* site.

Claim 49 (withdrawn): The method of claim 48, wherein the implantable device comprises a plurality of elastomeric matrices.

Claim 50 (previously presented): The implantable device of claim 11, wherein the elastomeric matrix has a compression set after 22 hours compression at about 25°C to 50% of its thickness in one dimension of not more than about 5%.

Claim 51 (previously presented): The implantable device of claim 12, wherein the elastomeric matrix is formed from an isocyanate component comprising diphenylmethane

diisocyanate, wherein the diphenylmethane diisocyanate is a mixture of at least about 5% by weight of 2,4'-diphenylmethane diisocyanate with the balance mainly 4,4'-diphenylmethane diisocyanate.

Claim 52 (previously presented): The process of claim 51, wherein the average number of isocyanate groups per molecule in the isocyanate component is greater than 2.

Claim 53 (previously presented): The process of claim 52, wherein the average number of isocyanate groups per molecule in the isocyanate component is greater than about 2.2.

Claim 54 (previously presented): The implantable device of claim 1, wherein the implantable device substantially fills the biological site in which it resides.

Claim 55 (previously presented): The implantable device of claim 13, wherein the reticulated elastomeric matrix is integrated into the tissue being repaired or replaced.

Claim 56 (withdrawn): A method of treating a vascular malformation, the method comprising inserting the implantable device of claim 1 by an open surgical procedure.

Claim 57 (withdrawn): A method of treating a vascular malformation, the method comprising inserting the implantable device of claim 1 by a delivery device.

Claim 58 (withdrawn): The process of claim 24, wherein the at least partially reticulated elastomeric matrix is configured to permit cellular ingrowth and proliferation into the at least partially reticulated elastomeric matrix.

Claim 59 (withdrawn): The process of claim 58, wherein the at least partially reticulated elastomeric matrix is integrated into the tissue being repaired or replaced.

Claim 60 (withdrawn): The product of the process of claim 46.

Claim 61 (withdrawn): The process of claim 47, wherein the bioabsorbable aliphatic polyester comprises lactic acid, glycolic acid, lactide, glycolide, para-dioxanone, trimethylene carbonate, ϵ -caprolactone, or any mixture thereof.

Claim 62 (withdrawn): The process of claim 26, wherein the polyol component, the isocyanate component, the blowing agent and, optionally, the catalyst, are admixed in a mixing vessel.

Claim 63 (withdrawn): The process of claim 26, wherein a first admixture comprising the polyol component, the blowing agent and, optionally, the catalyst is formed by admixing the polyol component, the blowing agent and the optional catalyst in a mixing vessel; and the first admixture is admixed with the isocyanate component.

Claim 64 (withdrawn): A process for preparing a reticulated elastomeric matrix, the process comprising reticulating the elastomeric matrix of claim 26 by a reticulation process to provide the reticulated elastomeric matrix.

Claim 65 (withdrawn): The reticulated elastomeric matrix of claim 64, wherein the reticulated elastomeric matrix substantially fills the biological site in which it resides.

Claim 66 (withdrawn): The process of claim 64, wherein the reticulated elastomeric matrix is configured to permit cellular ingrowth and proliferation into the reticulated elastomeric matrix.

Claim 67 (withdrawn): The process of claim 66, wherein the reticulated elastomeric matrix is integrated into the tissue being repaired or replaced.

Claim 68 (withdrawn): The product of the process of claim 31.

Claim 69 (withdrawn): The product of the process of claim 33.

Claim 70 (withdrawn): The product of the process of claim 35.

Claim 71 (withdrawn): The product of the process of claim 37.

Claim 72 (withdrawn): The product of the process of claim 39.

Claim 73 (withdrawn): The product of the process of claim 40.

Claim 74 (withdrawn): The product of the process of claim 41.

Claim 75 (withdrawn): The product of the process of claim 42.

Claim 76 (withdrawn): The product of the process of claim 43.

Claim 77 (withdrawn): The product of the process of claim 44.

Claim 78 (withdrawn): The product of claim 77, wherein the permeability to a liquid of the reticulated elastomeric matrix is greater than the permeability to the liquid of an unreticulated matrix from which the reticulated elastomeric matrix was made.

Claim 79 (withdrawn): The process of claim 26, wherein for every 100 parts by weight of polyol component, the process includes from about 10 to about 90 parts by weight of isocyanate component and from about 0.5 to about 5.0 parts by weight of blowing agent.

Claim 80 (withdrawn): The product of the process of claim 79.

Claim 81 (withdrawn): The product of claim 80, wherein the permeability to a liquid of the reticulated elastomeric matrix is greater than the permeability to the liquid of an unreticulated matrix from which the reticulated elastomeric matrix was made.

Claim 82 (withdrawn): The process of claim 79, wherein for every 100 parts by weight of polyol component, the process includes up to about 20 parts by weight of crosslinking agent, up to about 20 parts by weight of chain extender, from about 0.1 to about 0.8 parts by weight of blowing catalyst, up to about 0.3 parts by weight of gelling catalyst, from

about 0.5 to about 2.5 parts by weight of surfactant, and up to about 8 parts by weight of viscosity modifier.

Claim 83 (withdrawn): The product of the process of claim 82.

Claim 84 (withdrawn): The product of claim 83, wherein the permeability to a liquid of the reticulated elastomeric matrix is greater than the permeability to the liquid of an unreticulated matrix from which the reticulated elastomeric matrix was made.

Claim 85 (withdrawn): A polymerization process for preparing an elastomeric matrix, the process comprising admixing:

- a) 100 parts by weight of a polyol component comprising a difunctional polycarbonate diol,
- b) from about 10 to about 90 parts by weight of an isocyanate component with an average number of isocyanate groups per molecule of greater than 2 and comprising a mixture of at least about 5% by weight of 2,4'-diphenylmethane diisocyanate with the balance 4,4'-diphenylmethane diisocyanate,
- c) from about 0.5 to about 5.0 parts by weight of a blowing agent comprising water,
- d) optionally, a crosslinking agent,
- e) optionally, a chain extender,
- f) from about 0.1 to about 1.1 parts by weight of at least one catalyst,
- g) from about 0.5 to about 2.5 parts by weight of surfactant,
- h) up to about 8 parts by weight of a viscosity modifier comprising propylene carbonate, and
- i) a cell opener;

to provide the elastomeric matrix, wherein the isocyanate component has an isocyanate index of from about 0.9 to 1.029.

Claim 86 (withdrawn): The product of the process of claim 85.

Claim 87 (withdrawn): The process of claim 85, wherein the difunctional polycarbonate diol is 1,6-hexamethylene polycarbonate diol.

Claim 88 (withdrawn): The process of claim 87, wherein the isocyanate index is from about 0.98 to about 1.02.

Claim 89 (withdrawn): The product of the process of claim 88.

Claim 90 (withdrawn): A process for preparing a reticulated elastomeric matrix, the process comprising reticulating the elastomeric matrix of claim 88 by a combustion reticulation process to provide the reticulated elastomeric matrix.

Claim 91 (withdrawn): The product of the process of claim 90.

Claim 92 (withdrawn): The process of claim 85, wherein the crosslinking agent is present at up to about 20 parts by weight and comprises glycerol and the chain extender is present at up to about 20 parts by weight and comprises 1,4-butanediol.

Claim 93 (withdrawn): The product of the process of claim 92.

Claim 94 (withdrawn): A process for preparing a reticulated elastomeric matrix, the process comprising reticulating the elastomeric matrix of claim 92 by a combustion reticulation process to provide the reticulated elastomeric matrix.

Claim 95 (withdrawn): The product of the process of claim 94.

Claim 96 (withdrawn): The process of claim 92, wherein the difunctional polycarbonate diol is 1,6-hexamethylene polycarbonate diol.

Claim 97 (withdrawn): The process of claim 96, wherein the isocyanate index is from about 0.98 to about 1.02.

Claim 98 (withdrawn): The product of the process of claim 97.

Claim 99 (withdrawn): A process for preparing a reticulated elastomeric matrix, the process comprising reticulating the elastomeric matrix of claim 97 by a combustion reticulation process to provide the reticulated elastomeric matrix.

Claim 100 (withdrawn): The product of the process of claim 99.

Claim 101 (withdrawn): A process for preparing a reticulated elastomeric matrix, the process comprising reticulating the elastomeric matrix of claim 85 by a combustion reticulation process to provide the reticulated elastomeric matrix.

Claim 102 (withdrawn): The product of the process of claim 101.

Claim 103 (withdrawn): The process of claim 101, wherein the reticulated elastomeric matrix is configured to permit cellular ingrowth and proliferation into the reticulated elastomeric matrix.

Claim 104 (withdrawn): The process of claim 103, wherein the reticulated elastomeric matrix is integrated into the tissue being repaired or replaced.

Claim 105 (withdrawn): A process for preparing a reticulated elastomeric matrix implantable device comprising a pharmaceutically-active agent, the process comprising: admixing at least one pharmaceutically-active agent with a component used in forming the elastomeric matrix, forming the elastomeric matrix, and reticulating the elastomeric matrix by a reticulation process to provide the reticulated elastomeric matrix; or coating at least one pharmaceutically-active agent onto a reticulated elastomeric matrix.

Claim 106 (withdrawn): The process of claim 105, wherein the coating is an endoporous coating.

Claim 107 (withdrawn): The product of the process of claim 105.

Claim 108 (withdrawn): A polymerization process for preparing a soft-segment crosslinked elastomeric matrix, the process comprising admixing:

a) a polyol component comprising at least one polyol with average number of hydroxyl groups per molecule greater than about 2,

b) an isocyanate component,

c) a blowing agent,

d) optionally, a chain extender,

e) optionally, at least one catalyst,

f) optionally, a surfactant,

g) optionally, a viscosity modifier, and

h) optionally, a cell opener;

to provide a soft-segment crosslinked elastomeric matrix.

Claim 109 (withdrawn): The process of claim 108, wherein the at least one polyol with average number of hydroxyl groups per molecule greater than about 2 comprises a polycarbonate diol.

Claim 110 (withdrawn): The product of the process of claim 108.

Claim 111 (withdrawn): A process for preparing a reticulated elastomeric matrix, the process comprising reticulating the soft-segment crosslinked elastomeric matrix of claim 108 by a combustion reticulation process to provide the reticulated elastomeric matrix.

Claim 112 (withdrawn): The product of the process of claim 111.

Claim 113 (withdrawn): The process of claim 111, wherein the reticulated elastomeric matrix is configured to permit cellular ingrowth and proliferation into the reticulated elastomeric matrix.

Claim 114 (withdrawn): The process of claim 113, wherein the reticulated elastomeric matrix is integrated into the tissue being repaired or replaced.